BISMATROL - bismuth subsalicylate liquid Major Pharmaceuticals

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Maximum Strength Bis matrol

Active ingredient (in each 15 mL tbsp)

Bismuth subsalicylate 525 mg

Purpose

Upset stomach reliever and anti-diarrheal

Uses

relieves:

- diarrhea
- heartburn
- indigestion
- nausea
- upset stomach associated with these symptoms

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from children pox or flu-like symptoms should not use this product. when using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Contains salicylate. Do not take if you are

- allergic to salicylates (including aspirin)
- taking other salicylate products

Do not use if you have

- bloody or black stool
- an ulcer
- a bleeding problem

Ask a doctor before use if you have

- fever
- mucus in the stool

Ask a doctor or pharmacist before use if you are

- taking any drug for
- anticoagulation (thinning of the blood)
- diabetes
- gout

arthritis

When using this product

a temporary, but harmless darkening of the stool and/or tongue may occur

Stop use and ask a doctor if

- symptoms get worse
- ringing in the ears or loss of hearing occurs
- diarrhea lasts more than 2 days

If pregnant or breast feeding, ask a health professional before use. Keep out of reach of children.

In case of overdose, get medical help or contact a Poison control center immediately.

Directions

- shake well before use
- for accurate dosing, use dose cup
- adults and children 12 years and over: 1 dose (2 tbsp or 30 mL) every hour as needed
- do not exceed 4 doses (8 tbsp or 120 mL) in 24 hours
- use until diarrhea stops but not more than 2 days
- children under 12 years: ask a doctor
- drink plenty of clear fluids to help prevent dehydration caused by diarrhea

Other information

- each Tbsp contains: sodium 5 mg, salicylate 236 mg, potassium 15 mg
- protect from freezing
- avoid excessive heat (over 104°F or 40°C)
- TAMPER EVIDENT: Do not use if imprinted shrinkband is missing or broken.

Inactive ingredients

benzoic acid, D&C red 22, D&C red 28, flavor, hydroxy ethyl cellulose, potassium hydroxide, purified water, saccharin sodium, salicylic acid, simethicone, xanthan gum.

Principal Display Panel

Maximum Strength Bismatrol

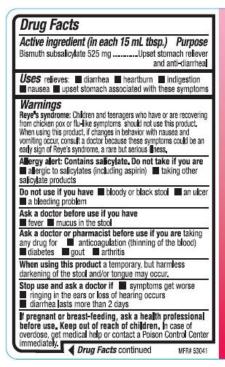
Soothing, coating action provides

fast relief for heartburn, indigestion, nausea, upset stomach and diarrhea

compare to the active ingredient in pepto-bismol® maximum strength

8 FL OZ (236 mL)

Maximum Strength Bismatrol





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*COMPARE TO THE ACTIVE INGREDIENT IN PEPTO-BISMOL® MAXIMUM STRENGTH.

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Drug Facts (continued)

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Questions or Comments? (800) 616-2471

*This product is not manufactured or distributed by Procter & Gamble, Inc., the distributor of Pepto-Bismol® Maximum Strength.

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31778 Enterprise Drive, Livonia, MI 48150 USA

Rev, 04/12 Re-Order No. 700283 M-30



BISMATROL

bismuth subsalicylate liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0904-1314

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthBISMUTH SUBSALICYLATE (UNII: 62TEY51RR1) (BISMUTH CATION -
UNII:ZS9CD1/8YE)BISMUTH
SUBSALICYLATE525 mg
in 15 mL

Inactive Ingredients	
Ingredient Name	Strength
BENZOIC ACID (UNII: 8 S KN0 B 0 MIM)	
D&C RED NO. 22 (UNII: 1678 RKX8 RT)	
D&C RED NO. 28 (UNII: 767IP0 Y5NH)	
HYDROXYETHYL CELLULOSE (2000 CPS AT 1%) (UNII: S38J6RZN16)	
PO TASSIUM HYDRO XIDE (UNII: WZH3C48 M4T)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
DIMETHICO NE (UNII: 92RU3N3Y1O)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics			
Color	pink	Score	
Shape		Size	
Flavor	WINTERGREEN	Imprint Code	
Contains			

l	Packaging				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:0904-1314-09	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/05/2009	12/31/2021	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part335	01/05/2009	12/31/2021	

Labeler - Major Pharmaceuticals (191427277)

Registrant - Guardian Drug Company (119210276)

Establishment				
Name	Address	ID/FEI	Business Operations	
Guardian Drug Company		119210276	manufacture(0904-1314)	

Revised: 12/2020 Major Pharmaceuticals